REMARKS/ARGUMENTS

Reconsideration of this Application and entry of this Amendment after Final are respectfully requested. The proposed amendment places the claims in better form for appeal. Additionally, this amendment addresses items brought up by the examiner in the final office action. In view of the amendments and following remarks, favorable consideration and allowance of the application is respectfully requested.

By the amendments, Applicants do not acquiesce to the propriety of any of the Examiner's rejections and do not disclaim any subject matter to which Applicants are entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997).

35 U.S.C. §102 Rejections

A claim is anticipated under 35 U.S.C. §102 only if each and every element as set forth in a claim is found, either expressly or inherently described, in a single prior art reference (MPEP §2131; *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d, 628, 631, 2 USPQ2d 1051 (Fed. Cir. 1987)). A claimed invention is anticipated only when it is "known to the art in the detail of the claim." *Karsten Manufacturing Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001). In other words, not only must the limitations of the claim be shown in a single prior art reference, the limitations must be "arranged as in the claim." *Id.*

Claims 1-3, 6, 7, 17-19, 40-42 have been rejected under 35 USC §102(e) as being anticipated by Jansen et al. (US 6,579,308). Applicant respectfully traverses.

Claim 1 has been amended to further characterize the stent as "contractable." Support for this amendment can be found, *iter alia*, in paragraph 0009 of the specification. Claims 2-6 have also been amended to conform the preamble of claims 2-6 to the preamble found in the remainder of the claims. No new matter was introduced as a result of these claim amendments. Claim 1, from which claims 2, 3, 6, 7, 17-19 and 40-42 depend, now reads "[a]n intravascular treatment device, comprising: a contractable stent locatable interior of an aneurysmal site in a blood vessel; wherein the stent supports the aneurysmal site upon deployment by engaging the inwardly-facing surface of the vessel wall, contracts when the aneurysmal site contracts due to healing, and comprises at least one therapeutic agent."

The Examiner states that on page 3 of the Office Action of June 15, 2007 and again on page 9 that the Jansen reference discloses a stent that contracts when the aneurysmal site contracts due to healing. Applicant is unable to find any such disclosure in Jansen. Jansen discloses stents and stent delivery systems that are self-expandable and/or self-forming and have detachable wires to allow the operator to manipulate the position and final configuration of the stent upon deployment (Jansen column 3, lines 48-53). Jansen does not disclose a stent which can circumferentially contract as time passes after deployment, such as when an aneurysm site contracts due to healing. Furthermore, Jansen states in column 7, lines 48-53 that "[t]he wire is typically of sufficient diameter to provide a hoop strength to the resulting device sufficient to hold the device in place within the chosen body cavity without distending the wall of the cavity and without moving from the cavity as a result of the repetitive fluid pulsing found in the vascular system." Therefore the hoop strength of the device is sufficient such that the device does not become altered after implantation and thus does not posses the characteristics to contract upon contraction of the aneurysm site due to healing.

Furthermore, the Examiner states that the stent of Jansen comprises nitinol, a super-elastic shape memory material. When cooled below its transition temperature range (TTR), the shape of a nitinol device (initial shape) can be deformed to compress into a delivery device. Upon raising the temperature of the device above the TTR, the device re-acquires its initial shape. The shape of the nitinol device cannot be changed as long as the device is maintained above the TTR. One of the useful characteristics of nitinol is its maintenance of its initial shape after placement in the body; nitinol is incompressible under outside pressure (US Patent No. 5,147,370, column 4 lines 37-39, a copy of which is attached hereto). Due to the physical properties of the stent, the nitinol stent disclosed by Jansen is physically unable to contract when an aneurysm site contracts due to healing, a requirement of the instant invention. Thus, Jansen does not enable the claimed contractable stent and furthermore does not disclose the claimed contractable stent, either expressly or inherently.

Because each and every element as set forth in amended claims 1-3, 6, 7, 17-19, 40-42, namely a contractable stent which contracts when the aneurysmal site contracts due to healing, was not found, either expressly or inherently, in Jansen et al., the pending claims are not

anticipated under 35 USC §102(b). The Examiner is respectfully requested to withdraw the rejection on that basis.

Claims 43-45 have been rejected under 35 USC §102(b) as being anticipated by Ragheb et al. (US 6,096,070). Applicants respectfully traverse.

Claim 43 has been amended to further characterize the stent as "contractable." Support for this amendment can be found, *iter alia*, in paragraph 0009 of the specification. Claim 43, from which claims 44 and 45 depend, now reads "[a]n intravascular treatment device, comprising a helical contractable stent locatable interior of an aneurysmal site in a blood vessel; wherein the stent supports the aneurysmal site upon deployment, contracts when the aneurysmal site contracts due to healing, and comprises at least one therapeutic agent.

Rahgeb does not disclose each and every element of claims 43-45. Ragehb discloses medical devices, particularly vascular stents, which provide a controlled release of a drug into a location in the body in which the medical device is positioned. The stents of Ragheb are designed to prevent restenosis or "abrupt reclosure" of a blood vessel (Ragheb column 2 lines 49-51). The stent is designed to "widen" narrowed vessels and keep them widened. The claimed invention is a stent permissive to circumferential contraction for treating an aneurysm site, which is an overly dilated artery, as it heals. Thus, Ragheb does not enable the claimed contractable stent and furthermore does not disclose the claimed contractable stent, either expressly or inherently.

Therefore, because each and every element as set forth in amended claims 43-45, namely a contractable stent that will contract when the aneurysmal site contracts due to healing, was not found, either expressly or inherently, in Ragheb et al., the pending claims are not anticipated under 35 USC §102(b). The Examiner is respectfully requested to withdraw the rejection on that basis.

35 U.S.C. §103 Rejections

Claims 4, 5, 8-16, 20-29, 31-39, and 46-48 have been rejected under 35 USC §103(a) as being unpatentable over Jansen '308 in view of Maass (US 4,553,545), Segal (US 5,755,708), Summers et al. (US 5, 772,668), Melzer et al. (US 6,280,385), Ragheb '070, Eisert *US 2005/0192664), Hunter et al. (US 6,333,347), Hunter et al. (US 5,716,981), Narciso, Jr. (US

5,419,760), Vallana et al. (US 2003/0028242), Clouse (US 5,21,658), and Falotico et al. (US 2003/0060877). Applicants respectfully traverse.

To reject a claim under 35 U.S.C. §103(a), the Examiner bears the initial burden of showing an invention to be *prima facie* obvious over the prior art. *In re Bell*, 26 USPQ.2d 1529 (Fed. Cir. 1992). If the Examiner cannot establish a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent. *In re Oetiker*, 24 USPQ.2d 1443 (Fed Cir. 1992).

Claims 4, 5, 8-18, 20-29 and 31-39 depend from independent claim 1 which is not anticipated by Jansen. Jansen discloses stents and stent delivery systems that are self-expandable and/or self-forming and have detachable wires to allow the operator to manipulate the position and final configuration of the stent upon deployment (Jansen column 3, lines 48-53). Jansen does not disclose a stent which can circumferentially contract as time passes after deployment, such as when an aneurysm site contracts due to healing. Furthermore, Jansen states in column 7, lines 48-53 that "[t]he wire is typically of sufficient diameter to provide a hoop strength to the resulting device sufficient to hold the device in place within the chosen body cavity without distending the wall of the cavity and without moving from the cavity as a result of the repetitive fluid pulsing found in the vascular system." Therefore the hoop strength of the device is sufficient such that the device does not become altered after implantation and thus does not posses the characteristics to contract upon contraction of the aneurysm site due to healing.

Furthermore, the Examiner states that the stent of Jansen comprises nitinol, a super-elastic shape memory material. When cooled below its transition temperature range (TTR), the shape of a nitinol device (initial shape) can be deformed to compress into a delivery device. Upon raising the temperature of the device above the TTR, the device re-acquires its initial shape. The shape of the nitinol device cannot be changed as long as the device is maintained above the TTR. One of the useful characteristics of nitinol is its maintenance of its initial shape after placement in the body; nitinol is incompressible under outside pressure (US Patent No. 5,147,370, column 4 lines 37-39, a copy of which is attached hereto). Due to the physical properties of the stent, the nitinol stent disclosed by Jansen is physically unable to contract when

an aneurysm site contracts due to healing, a requirement of the instant invention. Thus, Jansen does not teach the contractable stent of the instant claims.

None of the cited prior art, Maass, Segal, Summers, Melzer, Ragheb, Eisert, Hunter '347, Hunter '981, Narciso, Jr., Vallana, Clouse or Falotico, remedy the deficiencies of Jansen.

The Examiner alleges that the elements of claims 4 and 5 are disclosed by Jensen in view of Maass, Segal, Summers and Melzer. Claims 4 and 5 are dependent from independent claim 1 and incorporate all of the elements of claim 1, namely a contractable stent which contracts when the aneurysmal site contracts. As stated *supra*, Jansen does not teach or suggest a contractable stent which contracts when the aneurysmal site contracts. Maass teaches a device comprising a helical shaped coil spring which can be contracted or expanded by suitable mechanical means. The device of Maass can only be contracted or expanded with the mechanical means and will not contract in response to physiologic conditions, such as contraction of the stent as the aneurysm site contracts. Segal teaches a mechanical prosthesis deployment device for delivering an expandable stent similar to a balloon catheter which causes expansion of the stent without interrupting blood flow. Segal teaches maintaining expansion of stents so as to maintain patency of the stented vessel. Summers teaches stents comprising a continuous loop of material in a spiral or helical configuration to provide uniform support to a vessel wall. The stents of Summers have an expanded diameter that is mechanically compressed to deliver the stent to the treatment site whereupon the stent is released to assume its original expanded diameter. Summers teaches that the compressed state is temporary for the purposes of deploying the stent in a constricted vessel. Melzer teaches stents useful with magnetic resonance imaging processes to effect improved placement of the stent at a treatment site. Certain of the stents taught by Melzer have helical configuration.

Maass, Segal, Summers and Melzer, either singly or in combination, do not remedy the shortcomings of Jansen and the combination does not disclose each and every element of claims 4 and 5, namely a contractable stent which contracts when the aneurysmal site contracts due to healing.

The Examiner alleges that the elements of claims 8, 9, 11 and 12 are disclosed by Jensen in view of Ragheb. As stated *supra*, Jansen does not teach or suggest a contractable stent which

contracts when the aneurysmal site contracts. Claims 8, 9, 11 and 12 are dependent from independent claim 1 and incorporate all of the elements of claim 1, namely a contractable stent which contracts when the aneurysmal site contracts. Ragheb teaches medical devices, particularly vascular stents, that provide controlled release of a drug into a location in the body in which the medical device is positioned.

Ragheb does not remedy the shortcomings of Jansen and the combination does not disclose each and every element of claims 8, 9, 11 and 12, namely a contractable stent which contracts when the aneurysmal site contracts due to healing.

The Examiner alleges that the elements of claim 10 is disclosed by Jensen in view of Ragheb and Wright (US 6,273,913). Claim 10 is dependent from independent claim 1 and incorporate all of the elements of claim 1, namely a contractable stent which contracts when the aneurysmal site contracts. As stated *supra*, Jansen does not teach or suggest a contractable stent which contracts when the aneurysmal site contracts. Ragheb was discussed *supra*. Wright teaches the localized delivery of rapamycin from an intravascular stent to inhibit neointimal tissue proliferation and thereby prevent restenosis.

Ragheb and Wright, either singly or in combination, do not remedy the shortcomings of Jansen and the combination does not disclose each and every element of claim 10, namely a contractable stent which contracts when the aneurysmal site contracts due to healing.

The Examiner alleges that the elements of claims 13-16 are disclosed by Jensen in view of Eisert, Ragheb and Hunter '347. Claims 13-16 are dependent from independent claim 1 and incorporate all of the elements of claim 1, namely a contractable stent which contracts when the aneurysmal site contracts. As stated *supra*, Jansen does not teach or suggest a contractable stent which contracts when the aneurysmal site contracts. Eisert teaches endoprosthetic devices for implantation in a vessel and simultaneous administration of a therapeutic compound. Furthermore, Eisert teaches that the expanded state of the stent is stable. Ragheb was discussed *supra*. Hunter '347 teaches methods for administration of a microtubule agent intrapericardially.

Eisert, Ragheb and Hunter '347, either singly or in combination, do not remedy the shortcomings of Jansen and the combination does not disclose each and every element of claims

13-16, namely a contractable stent which contracts when the aneurysmal site contracts due to healing.

The Examiner alleges that the elements of claims 20-27 are disclosed by Jensen in view of Narciso, Jr. Claims 20-27 are dependent from independent claim 1 and incorporate all of the elements of claim 1, namely a contractable stent which contracts when the aneurysmal site contracts. As stated *supra*, Jansen does not teach or suggest a contractable stent which contracts when the aneurysmal site contracts. Narciso Jr. teaches methods of treating vascular diseases postcanalization to prevent restenosis by providing a bioabsorbable stent which releases a medicament.

Narciso, Jr. does not remedy the shortcomings of Jansen and the combination does not disclose each and every element of claims 20-27, namely a contractable stent which contracts when the aneurysmal site contracts due to healing.

The Examiner alleges that the elements of claims 28, 29, 31-33, 36-39 and 48 are disclosed by Jensen in view of Hunter '981. Claims 28, 29, 31-33 and 36-39 are dependent from independent claim 1 and claim 48 is dependent from independent claim 43 and incorporate all of the elements of claims 1 and 43, respectively, namely a contractable stent which contracts when the aneurysmal site contracts. As stated *supra*, Jansen does not teach or suggest a contractable stent which contracts when the aneurysmal site contracts. Hunter '981 teaches anti-angiogenic compositions, as well as methods and devices which utilize such compositions for the treatment of cancer and other angiogenesis-dependent diseases. Hunter '981 also teaches embolizing a blood vessel. Additionally, Hunter '981 teaches stents having the surface coated with one or more anti-angiogenic compositions and methods for expanding the passageway of a body lumen.

Hunter '981 does not remedy the shortcomings of Jansen and the combination does not disclose each and every element of claims 28, 29, 31-33, 36-39 and 48, namely a contractable stent which contracts when the aneurysmal site contracts due to healing.

The Examiner alleges that the elements of claims 31-36 are disclosed by Jensen in view of Ragheb and Vallana. Claims 31-36 are dependent from independent claim 1 and incorporate all of the elements of claim 1, namely a contractable stent which contracts when the aneurysmal site contracts. As stated *supra*, Jansen does not teach or suggest a contractable stent which

contracts when the aneurysmal site contracts. Ragheb was discussed *supra*. Vallana teaches a stent with a radially expandable tubular body and an active agent for treatment of the implant site.

Ragheb and Vallana, either singly or in combination, do not remedy the shortcomings of Jansen and the combination does not disclose each and every element of claims 31-36, namely a contractable stent which contracts when the aneurysmal site contracts due to healing.

The Examiner alleges that the elements of claims 46 and 47 are disclosed by Jensen in view of Clouse and Falotico. Claims 46 and 47 are dependent from independent claim 43 and incorporate all of the elements of claim 43, namely a contractable stent which contracts when the aneurysmal site contracts. As stated *supra*, Jansen does not teach or suggest a contractable stent which contracts when the aneurysmal site contracts. Clouse teaches a blood vessel wall-defining device for repairing an aneurysm comprising a structural frame and a thin-walled flexible tubular membrane, the thin-walled flexible tubular membrane held against the vessel wall by the structural frame. Falotico teaches medical devices for the treatment of vascular disease wherein the medical device comprises a scaffold structure for maintaining luminal patency and a biocompatible vehicle for the controlled release of one or more therapeutic agents.

Clouse and Falotico, either singly or in combination, do not remedy the shortcomings of Jansen and the combination does not disclose each and every element of claims 46 and 47, namely a contractable stent which contracts when the aneurysmal site contracts due to healing.

Furthermore, at least Hunter '981, Vallana, Falotico, Narciso, Jr., Maass, Segal, Ragheb and Summers teach away from a stent which contracts when the aneurysmal site contracts because the stents disclosed in these documents are for treating restenosis and preventing abrupt reclosure and therefore their purpose is to prevent closure or narrowing of the vessel. In order to accomplish this function, the stent must exert an outward pressure on the vessel wall to maintain the expanded state, regardless of any healing activity in the vessel. If the stents of Hunter '981, Vallana, Falotico, Narciso, Jr., Maass, Segal, Ragheb and Summers were able to contract when the vessel contracts, this function would be lost, the vessel would close and the stent would be inoperable for its intended purpose, that is, expanding the lumen of the vessel. Therefore, these

prior art documents are addressing a different problem, preventing narrowing or closure of a blood vessel, than the instant claims.

Therefore the Examiner has not established *prima facie* obviousness of claims 4, 5, 8-16, 20-29, 31-39 and 46-48 over Jensen in view of Maass, Segal, Summers, Melzer, Raheb, Eisert, Hunter '347, Hunter '981, Narciso, Jr., Vallana, Clouse and Falotico and Applicants respectfully request the withdrawal of the outstanding rejection on this basis.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 566-1888.

Respectfully submitted,

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